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EXAMINER

FLOOD, MICHELE C

ART UNIT PAPER NUMBER

1654

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,335

Applicant(s)

NEWMAN ET AL.

Examiner

Michele C. Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/02/9/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-8, on December 29, 2003 is acknowledged. The traversal is on the grounds that Claim 9 has been amended to include four process steps as recited in independent Claim 1. This is not found persuasive because while the invention of Group I, Claims 1-8 is directed to a method for forming a protein and carotenoid product, comprising the steps (a) preparing a solution of a carotenoid in a solvent; (b) adding a source of metal ions; (c) adding a source of protein; and (d) incubating the solution; the invention of Group II, Claim 9, is directed to a method for forming a protein and carotenoid product, comprising the steps of: (a) preparing a protein-containing mixture; (b) providing a source of carotenoids; (c) providing a source of metal ions; and (d) heating the mixture.

As readily admitted by Applicant, there are differences between independent claims, Claim 1 and Claim 9. While Applicant argues that the principle ingredients of a protein, a carotenoid, a source of metal ions and heat of the mixture are directed to a single inventive concept, the Office notes that two inventions above are independent and distinct, each from the other. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the parenthetical expression "carotene" renders the claim indefinite because it is unclear if the phrase is intended to be a limitation of the claimed subject matter.

Claim 5 appears to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B, and C". See *Ex parte Markush*, 1925 C. D. 126 (Comm'r Pat. 1925).

Regarding Claim 7, lines 2-3, the phrase "(i.e., bovine and chicken)" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Regarding Claim 7, lines 4-5, there is an apparent misplacing of a comma in the phrase "soybean proteinase inhibitors, comprising Kunitz, Bowman-Birk, and carboxypeptidase inhibitors." Appropriate correction is required because at present it is unclear as to the subject matter Applicant intends to direct the invention.

Claim 8, line 1, recites the limitation "the step of drying". There is insufficient antecedent basis for the limitation in the claim. Applicant may overcome the rejection by replacing "the" with a.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster (A).

Applicant claims a method for forming a protein and carotenoid product, comprising the steps of: (a) preparing a solution of a carotenoid in a solvent; (b) adding a source of metal ions; (c) adding a source of protein; and (d) incubating the solution. Applicant further claims a method as defined in claim 1, wherein the carotenoid comprises esters of hydroxyl- or carboxyl-containing carotenoid. Applicant further claims a method as defined in claim 1, wherein the carotenoid is selected from the group comprising actinioerythrol, astaxanthin, bixin, canthaxanthin, capsanthin, capsorubin, β -8'-apo-carotenal (apo-carotenal), β -12'-apo-carotenal, α -carotene, β -carotene, "carotene" (a mixture of α - and β -carotenes), γ -carotene, β -cryptoxanthin, lutein, lycopene, violerythrin, zeaxanthin, and esters of hydroxyl- or carboxyl-containing members thereof. Applicant further claims a method as defined in claim 1, wherein the carotenoid comprises xanthophylls and esters of hydroxyl- or carboxyl-containing

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members thereof. Applicant claims a method as defined in claim 1, wherein the metal ions are selected from the group comprising Mg^{++} , Mn^{++} , K^+ , and Ca^{++} . Applicant further claims a method as defined in claim 1, wherein the protein source is selected from the group comprising soybean proteins and isolates; albumin from various sources; whey proteins, concentrates and isolates; isoflavone containing protein products; corn germ proteins; oat flour; soybean proteinase inhibitors; comprising Bowman-Birk, and carboxypeptidase inhibitors; potato proteinase inhibitors; and hydrolyzed vegetable proteins. Applicant further claims a method as defined in claim 1, further comprising the step of drying to form a dry product containing the protein and carotenoid product.

Webster teaches a method for forming a protein and carotenoid tobacco product comprising the claimed process steps and ingredients. In Column 2, lines 35-41, Webster teaches carotenoids, such as, β -carotene, α -carotene, admixtures of α -carotene and β -carotene with γ -carotene, lycopene, 15^1 , 15^1 -dehydro- β -carotene, 4 , 4^1 -diketo- 15 , 15^1 -dehydro- β -carotene, bixin, apocarotenal, apocarotenoic acid derivatives, canthaxanthin or other xanthophylls, that are useful in the making of the products of his invention. In Column 3, lines 9-21, Webster teaches proteins, such as, albumin, casein, gelatine, peptone, hemoglobin or wool protein, and vegetable proteins, *e.g.*, protein from maize (zein), wheat (glutin and gliadin), soyabean or groundnut, and protein acid hydrolysates and protein enzyme hydrolysates, *e.g.*, casein acid hydrolysate and casein enzyme hydrolysate, are useful in the making of the product of his invention. In Column 2, lines 3-6, Webster further teaches alkali metals or alkaline earth metals are useful in the making of his invention, also. As an example, in Column

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7, line 64 to Column 8, line 12, Webster teaches preparing a solution of carotene in a chloroform solvent, which was added to a solution of glycerol, water, sodium carboxymethyl cellulose, magnesium carbonate, calcium carbonate, soya fibre protein, bentonite, alpha-cellulose and ammonium sulphamate and allowing the chloroform solvent to evaporate.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakado et al. (N) in view of Yemelyanov et al. (U1).

Sakado teaches a method of making a protein and carotenoid product comprising adding an astaxanthin fatty acid ester to feed. Sakado teaches treating astaxanthin in tetrahydrofuran (THF, solvent) with pyridine and palmitoyl chloride (a source of metal ions, Ca^{++}), which was mixed with white fish meal, starch, beer yeast, soybean cake (source of protein), minerals and water.

The teachings of Sakado are set forth above. Sakado teaches the claimed method except for incubation. However, it would have been obvious to one of ordinary skill in the art to optimize the method of making a protein and carotenoid product taught

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by Sakado by adding the instantly claimed process step of incubation to the Sakado' method to provide the claimed invention because at the time the invention was made the instantly claimed process step was known in the art to augment the binding of a carotenoid to a protein, as evidenced by the teachings of Yemelyanov. For instance, on page 4, Column 2, lines 1-12, Yemelyanov teaches a method of adding carotenoids dissolved in tetrahydrofuran to a protein preparation (XBP), and incubating the solution overnight. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to optimize the method of forming a protein and carotenoid product taught by Sakado by adding the instantly claimed process of incubation because Yemelyanov teaches tetrahydrofuran is a preferred solvent for delivery of carotenoids to aqueous environments and that incubation of a carotenoid dissolved in tetrahydrofuran with a protein augments binding of carotenoids and protein within a short period of time; and, Sakado teaches that combining astaxanthin dissolved in tetrahydrofuran and a source of a metal ion with a protein source provides stabilizes the astaxanthin esters.

With regard to Claim 8 wherein Applicant claims a method as defined in Claim 1 further comprising a step of drying to form a dry product containing the protein and carotenoid product, at the time the invention was made it would have been obvious to one of ordinary skill in the art, and one would have been motivated and would have had a reasonable expectation of success to optimize the method of making the carotenoid and protein product taught by the combined aforementioned teachings to provide the claimed invention because the claimed step of drying would have merely a matter of

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experimental design choice to one practicing the invention at the time the invention was made, since the drying of food products are routine and well known in the art of food processing.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients and instant process steps for forming a protein and carotenoid product for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties and process steps of known result-effect variables where the results obtained thereby are no more than the additive effect of the ingredients and process steps, *In re Sussman*, 1943 C.D. 518.

Thus, the claimed invention is no more than the additive effects of known methods using known ingredients, which are notoriously old and well known in the art for forming a protein and carotenoid product.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Claims 1-5 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (A).

Applicant's claimed invention was set forth above.

The teachings of Webster are set forth above. Although Webster does not expressly teach a process step of incubation *per se*, Webster does teach evaporation of the solvent comprising the carotenoid. At the time the invention was made, one of ordinary skill in the art would have been motivated, and one would have been motivated to optimize the process step of evaporation taught by Webster by incubating the incubating the protein and carotenoid product during the step of evaporation because one would have had a reasonable expectation of success that the incubation of the Webster' product during the evaporation process would facilitate the evaporation of the solvent contained therein.

Thus, the effective varying of the experimental conditions of the evaporation process taught by Webster would have been no more than a routine matter of optimization for one of ordinary skill in the art at the time the invention was made.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele C. Flood whose telephone number is (571) 272-0964. The examiner can normally be reached on 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PATENT EXAMINER

MCF

April 5, 2004